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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,468	09/12/2000	Allan S. Lau	4099-0002.31	6858

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,468

Applicant(s)

LAU ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,10 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,9,10 and 25-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0503</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/21/2004 has been entered.

Claims 1, 2, 9, 10, 25-29 are pending. Claims 9, 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9. Claims 1, 2, 10, 25-27 are being examined to the extent that they read upon a composition comprising IFN- α and IFN- β .

15 **Maintained Formal Matters, Objections, and/or Rejections:**

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See page 17, line 6.

It is acknowledged that Applicants have submitted a paper copy and computer readable form of the sequence listing. However, the present specification does not make a reference to the sequence at page 17, line 6, by use of the sequence identifier, preceded by "SEQ ID NO: ". Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing," reference must be made to the

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sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Correction is required.

5

Claim Rejections - 35 USC § 102

Claims 1, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau (N, Paper No. 10), as evidenced by Der (U, Paper No. 10).

Applicants argue that there is no basis for asserting that the claimed product is the same or similar to that of Lau. Applicants' arguments have been fully considered but they are not persuasive. Even though the present product claims are limited by and defined by the recitation of a process limitation, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Lau discloses a composition comprising a mixture of human IFN- α and IFN- β . No difference is seen between Lau's composition and the claimed composition even though the claimed composition is made by a different process. Applicant has the burden to come forward with evidence establishing a novel or unobvious difference between Lau's composition and the claimed composition. Applicants' arguments only establish that the claimed composition is produced by a process that is different from Lau's process.

Claim Rejections - 35 USC § 103

Claims 1, 2, 10, 25, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Kurimoto (A, Paper No. 10) in view of Shimizu (B, Paper No. 10).

Applicants argue that producing the mixture of cytokines in the manner described
5 and claimed provides two important advantages. Applicant's arguments have been fully considered but they are not persuasive. Applicants are describing advantages of their process. However, the claims are to a product. Although Applicants process may have certain advantages, the patentability of the claimed product is based on the product itself. The patentability of a product does not depend on its method of production. Therefore,
10 Applicants' arguments are not persuasive

Applicants argue that Kurimoto is not concerned with the problem addressed by Applicants, nor does it suggest Applicants' solution, and that Kurimoto does not teach or suggest Applicants' process.

Applicants argue that Shimizu is not concerned with the problem addressed by
15 Applicants, nor does it suggest Applicants' solution or the advantages thereof.

Applicants argue that the examiner has not made a prima facie case for obviousness, and that the prior art cannot be said to provide a suggestion or motivation for the claimed invention.

Applicant's arguments have been fully considered but they are not persuasive.
20 The claims are to a product. Although Applicants process may have certain advantages, the patentability of the claimed product is based on the product itself. The patentability of a product does not depend on its method of production.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a cytokine mixture ... that is stoichiometrically similar to that produced physiologically") are not recited in the rejected claim(s). Although the claims are
5 interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871
10 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, Kurimoto in view of Shimizu provides a suggestion and motivation to make the claimed composition because Kurimoto teaches that the combination of HuIFN- γ with HuIFN- α and/or HuIFN- β augments the antiviral, cytostatic and antioncotic activities of HuIFN- γ , and Shimizu provides a source of affinity purified IFN-
15 α and IFN- β .

Double Patenting

Claims 1, 2, 10, 25, 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 15-22 of copending Application No. 10105100. Applicants' request to hold this rejection in
20 abeyance is acknowledged. However, there are no provisions for holding a rejection in abeyance.

Claim Rejections - 35 USC § 112

Claims 1, 2, 10, 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "overexpression" in claim 1 is a
5 relative term which renders the claim indefinite. The term "overexpression" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. The metes and bounds are not clearly set forth.

Applicants argue that the term "overexpression" is defined on page 4, line 31.
10 Applicant's arguments have been fully considered but they are not persuasive. The definition of "overexpression" provided in the paragraph bridging pages 4-5, occurs in the context of "higher than normal levels of cytokine-regulating factor activity." The specification goes on to state that "normal" cytokine-regulating factor activity or expression is reported as a range of cytokine-regulating factor activity or expression,
15 which is *generally* observed for a given type of cells which have not been transfected with a vector encoding the cytokine-regulating factor, are unstimulated (not induced or primed) and uninfected (emphasis added). It will be understood that the range of normal cytokine-regulating factor activity will vary dependent upon the particular factor, cell type and for a given cell type may vary somewhat dependent upon culture conditions.
20 However, this definition provided in the paragraph bridging pages 4-5 of the present specification does not reasonable apprise one of ordinary skill in the art of the metes and bounds of the claimed invention.

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New Formal Matters, Objections, and/or Rejections:***Double Patenting***

Claims 1, 2, 10, 25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10241970. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are generic to and fully encompass the claims of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 26 is objected to because of the following informalities: the term "comprises" should be "comprise." Appropriate correction is required.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

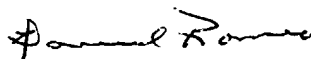
BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
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